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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/549,937 04/14/00 CHANCELLOR

M 2710-4007US2

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HM22/0928

EXAMINER

WHITEMAN, B

ART UNIT

PAPER NUMBER

1633

DATE MAILED:

09/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/549,937

Applicant(s)

CHANCELLOR ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-99 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Claims 1-99 are pending and under consideration in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 17-27, 45-55, 84, and 92-96, drawn to an isolated muscle-derived cell having a long term survivability when introduced into mammals, wherein the cells express cell markers selected from the group consisting of at least domains desmin, CD34, and Bcl-2, a method of augmenting or bulking muscle tissue in a mammal, a method of treating a weakness or dysfunction in a muscle tissue, classifiable in class 435, subclass 325.
- II. Claims 4-16, 28-44, 56-83, and 85-87, drawn to a method of augmenting or bulking non-muscle soft tissue, a method of treating a defect in non-muscle soft tissue in a mammal, a method of augmenting or bulking a non-muscle, non-bone soft tissue in a mammal, a method of treating a defect in a bone or a non-muscle soft tissue comprising: administering to the bone or non-muscle tissue the composition according to claim 3, wherein the cells comprise heterologous DNA encoding one or more active biomolecules, and wherein biomolecules are expressed by the cells, thereby treating the defect, classifiable in class 424, subclass 93.1, subclass 93.2.
- III. Claims 88-91 and 97-99, drawn to a method of treating gastro esophageal reflux, a method of restoring or improving contractility of smooth muscle tissue, classifiable in class 424, subclass 93.1, subclass 93.2.

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The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Invention I is a product encompassing isolated muscle-derived cells, wherein the cell express cell markers selected from the group consisting of at least desmin, CD34, and Bcl-2. Inventions II-III are patentably distinct methods of using the product of invention I. Thus, the product in group I as claimed can be used in a materially different process of using the product as shown in groups II-III.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because each of the methods of inventions I-III constitutes patentably distinct inventions for the following reasons: Each of the inventions is directed to different goals and comprises materially distinct steps, wherein each of the compositions in each invention is structurally distinct and/or generates distinct mechanisms and functional effects as indicated above. The scope of each of the cited inventions encompasses an employed method, which generates distinct function(s) and effect(s), and furthermore does not necessarily overlap with that of another invention. Furthermore, the method of I is not encompassed by II-III. In addition, each invention is a patentably distinct method of using the product as discussed above. Each of the inventions I-III comprises materially distinct steps, and/or generates different functions and effects, and thus, is not required for use with one another.

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If applicants elect group I, claim 17 and claims dependent therefrom are generic to a plurality of disclosed patentably distinct species comprising: digestive, reproductive, cardiovascular, urological, and respiratory. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (*e.g.* digestive, reproductive, cardiovascular, urological, and respiratory), even though this requirement is traversed.

Furthermore, if applicants elect group I, claim 45 and claims dependent therefrom are generic to a plurality of disclosed patentably distinct species comprising: esophageal, anal, cardiac, pyloric, and urinary sphincter tissue. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (*e.g.* esophageal, anal, cardiac, pyloric, and urinary sphincter tissue), even though this requirement is traversed.

If applicants elect group II, claims 4, 28, 56, 85 and claims dependent therefrom are generic to a plurality of disclosed patentably distinct species comprising: non-muscle soft tissue; non-muscle, non-bone soft tissue; or bone. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Furthermore, if applicants elect group II, claims 4, 28, and claims dependent therefrom are generic to a plurality of disclosed patentably distinct species comprising: digestive, reproductive, cardiovascular, urological, neural, respiratory, epithelial, dermal, and connective tissue. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (*e.g.* digestive, reproductive, cardiovascular, urological, neural, respiratory, epithelial, dermal, and connective tissue), even though this requirement is traversed.

In addition, if applicants elect group II, claims 85, 86 and claims dependent therefrom are generic to a plurality of disclosed patentably distinct species comprising: cell growth factors, cell

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differentiation factors, cell signaling factors, and programmed cell death factors. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (*e.g.* cell growth factors, cell differentiation factors, cell signaling factors, and programmed cell death factors), even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and the literature search required for Group I is not required for Group II-III, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Tracey Johnson whose telephone number is (703) 305-2982.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775.


The examiner can normally be reached on M-F, (730-400 EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached at (703) 305-4051.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-8724.

Brian Whiteman, 1633
9/28/01


DAVE T. NGUYEN
PRIMARY EXAMINER